ASX Release

15 April 2021

Acrux's fourth generic dossier accepted by FDA for review

Melbourne, Australia; 15 April 2021: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review Acrux's Abbreviated New Drug Application (ANDA) for its generic version of Dapsone Gel, 7.5%.

Key Highlights

- Acrux has submitted an ANDA application to the FDA for Dapsone Gel, 7.5%, which has now been accepted for review
- Annual sales for the product exceeded US$206 million as measured by IQVIA [1]
- The product is used to treat acne vulgaris (common acne)
- The announcement marks Acrux's fourth ANDA accepted for review by the FDA
- Acrux's ANDA submission includes a Paragraph IV certification against the Orange Book listed patents [2]

Acrux CEO and Managing Director, Michael Kotsanis said:

"The Dapsone Gel, 7.5% market is a significant market opportunity. Acrux is pleased to submit this ANDA as an important step to future commercialisation and market access of an affordable generic product."

FDA accepts for review Acrux's ANDA submission

In March 2021, Acrux submitted an ANDA to seek approval from the FDA to market its generic version of Dapsone Gel, 7.5%. The FDA has notified Acrux that the submission is sufficiently complete to be accepted for review.

The reference listed drug is Aczone® marketed by Almirall LLC in the United States. Aczone® is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Once granted final approval by the FDA, Acrux will be permitted to commence sales and marketing of the product in the United States.

[1] IQVIA September 2020 MAT. Annual product sales for previous twelve months is the addressable market.

[2] The publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

US$206 million annual market size

The total annual addressable market for the product including existing generics is US$206 million. There is currently 1 approved ANDA for a generic version of the product.

Paragraph IV certification

Acrux has submitted a Paragraph IV certification along with its ANDA submission. This certification declares the two patents listed in the FDA Orange Book are either invalid, unenforceable and/or would not be infringed by Acrux ANDA product. The basis for Acrux's paragraph IV certification is sent to the patent owner who then has 45 days to initiate patent litigation proceedings.

Acrux product portfolio

Acrux now has three ANDAs under review by the FDA along with one ANDA approved earlier in 2021. In addition, the Company has two commercialised products marketed in over 30 countries and a strong history of development and commercialisation of topical pharmaceutical products.

Approved for release by the Acrux Board of Directors.

For more information, please contact:

Michael Kotsanis
Acrux Limited
CEO & Managing Director
P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is developing of a range of generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

For further information on Acrux, visit www.acrux.com.au